

Applicant : Khosravi, et al.
Appl. No. : 09/427,260
Examiner : B. Pelegriño
Docket No. : 702563.4004

Remarks

Claims 29-30, 55-57, and 59-62 are pending. In the Office Action, the Examiner rejected all pending claims under 35 U.S.C. § 102(e), and claims 29, 30, 56, and 60 were rejected under 35 U.S.C. § 103(a). By this amendment, claims 59 and 62 are amended, and claim 61 is cancelled.

Applicant respectfully requests reconsideration of the application and claims in view of the present amendment, the following Remarks, and the expert testimony of Eric Leopold contained in the Rule 132 Declaration submitted previously.

Claim Rejections – 35 U.S.C. § 102(e) based upon Fogarty

The Examiner rejected claims 55, 57, 59, 61, and 62 as being anticipated by United States Patent No. 5,800,520 to Fogarty et al. Applicants respectfully request reconsideration and withdrawal of this rejection.

The rejected claims include limitations directed to the nature of the stretchable cells or stretchable elements that are not disclosed, taught, or suggested by the Fogarty patent. For example, claim 55 recites the following:

a plurality of stretchable cells formed in the coiled-up sheet, each stretchable cell comprising a pair of peripherally expandable wing-like elements extending generally parallel to the longitudinal axis, each of said wing-like elements comprising first and second members having undulations

By dependence, this limitation is also contained in claim 57. Similarly, claim 59 recites the following:

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a plurality of stretchable elements formed in the coiled-up sheet, wherein each stretchable element comprises a pair of peripherally expandable wing-like elements extending generally parallel to the longitudinal axis, each of said wing-like elements comprising first and second members having undulations.

Claim 62 also contains this limitation due to its dependence on claim 59. Claim 61 has been cancelled.

On the other hand, the Fogarty et al. patent describes and illustrates stents having generally straight struts, and therefore does not disclose, teach or suggest the claimed "wing-like elements extending generally parallel to the longitudinal axis." The Examiner refers to a portion of the Fogarty patent at column 4, lines 65-67, which states that the "tubular member" may be constructed of "serpentine elements" among other structures. The Examiner states that:

It is noted that Fogarty discloses that flexible or expandable elements can be formed with a serpentine pattern, which inherently forms wing-like elements with undulations, col. 4, lines 65-67.

Applicants disagree with this extrapolation from the teachings of the Fogarty patent. To establish inherency, the Examiner must show that the teachings of the Fogarty patent would necessarily include the claim limitations at issue, and that such inclusion would be recognized by persons of ordinary skill in the art. See Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). It is not enough to show that the result may occur:

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Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

Id. at 1269. In this case, even if the "serpentine elements" taught by Fogarty would result in a tubular member having "wing-like elements with undulations," those elements would not necessarily be formed in such a way that they extend "generally parallel to the longitudinal axis," as claimed. Accordingly, these limitations recited in the claims at issue are not disclosed, either explicitly or inherently, by the Fogarty patent.

For these reasons, Applicants respectfully request reconsideration and withdrawal of this basis for rejection of claims 55, 57, 59, and 62.

Claim Rejections – 35 U.S.C. § 102(e) based upon Khosravi

The Examiner rejected all claims as being anticipated by United States Patent No. 5,824,054 to Khosravi et al. ("Khosravi '054"). Applicants respectfully request reconsideration and withdrawal of this rejection.

Turning first to claims 29 and 30, claim 29 (and, by dependency, claim 30) includes recitation of:

a plurality of stretchable elements formed in the coiled-up sheet, the stretchable elements having a shape memory such that the stretchable elements are plastically deformable towards an unstretched condition at a temperature at or below about 25 degrees Celsius, and biased to expand about the periphery from the unstretched condition towards a stretched condition when exposed to a temperature at or above body temperature;

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The Khosravi '054 patent fails to teach, disclose, or suggest the claimed stretchable elements.

The Examiner contends that the graft stent illustrated in FIG. 6 of the Khosravi '515 patent meets the above limitations, and that Khosravi '054 describes that the graft stent "is formed of shape memory material, col., 5, lines 55-67." Applicants respectfully disagree. The Khosravi '054 patent does not disclose "stretchable elements" that are "plastically deformable" and that "expand about the periphery from the unstretched condition towards a stretched condition." The "articulations 52" of the Khosravi '054 patent – which the Examiner refers to as being "stretchable elements" – are described in the Khosravi '054 patent as being included to provide greater flexibility to the graft stent for passing through tortuous body lumens. (Col. 9, ll. 35-38). There is no description to support the contention that these "articulations" are stretchable, nor that they are "biased to expand" from an unstretched condition to a stretched condition. For these reasons, Applicants respectfully request reconsideration and withdrawal of the rejections of claims 29 and 30 based upon the Khosravi '054 patent.

Turning next to claims 55 through 57, claim 55 (and, by dependency, claims 56 and 57) includes recitation of:

a plurality of stretchable cells formed in the coiled-up sheet, each stretchable cell comprising a pair of peripherally expandable wing-like elements extending generally parallel to the longitudinal axis . . . , the wing-like elements being expandable about the periphery between an unstretched condition to facilitate placement in a delivery device in the contracted condition and a stretched condition to facilitate expansion of the coiled-up

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sheet to the one or more enlarged conditions upon deployment from the delivery device.

As noted above, the Khosravi '054 patent does not disclose, teach, or suggest "wing-like elements" that are expandable from an unstretched condition to a stretched condition. For these reasons, Applicants respectfully request reconsideration and withdrawal of the rejections of claims 55 through 57 based upon the Khosravi '054 patent.

Finally, turning to claims 59-62, claim 61 has been cancelled, and its limitations have been added to claim 59. Accordingly, claim 59 now recites that:

the stretchable elements have a shape memory such that the stretchable elements are plastically deformable towards an unstretched condition at a first temperature, and biased to expand about the periphery from the unstretched condition towards a stretched condition when exposed to a temperature at or above a second temperature

As noted above, the Khosravi '054 patent does not disclose, teach, or suggest "stretchable elements" that are plastically deformable from an unstretched condition to a stretched condition. For these reasons, Applicants respectfully request reconsideration and withdrawal of the rejections of claims 59 and 62 based upon the Khosravi '054 patent.

Claim Rejections – 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 29, 30, 56 and 60 for obviousness over the Fogarty patent in view of U.S. Patent No. 5,441,515 ("the Khosravi '515 patent").

Applicant requests reconsideration and withdrawal of these rejections.

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As an initial matter, Applicant repeats the grounds set forth above concerning the Examiner's rejection of claims for anticipation. As stated there, the Fogarty patent fails to disclose, teach, or suggest the following limitations recited in each of claims 29, 30, 56, and 60. Specifically, claim 29 (and claim 30, which depends from claim 29), recites:

wherein each stretchable element comprises a pair of peripherally expandable wing-like elements extending generally parallel to the longitudinal axis.

As noted above, the Fogarty patent does not describe wing-like elements that extend "generally parallel to the longitudinal axis" of the tubular element. Similarly, claim 55 (from which claim 56 depends) recites:

a plurality of stretchable cells formed in the coiled-up sheet, each stretchable cell comprising a pair of peripherally expandable wing-like elements extending generally parallel to the longitudinal axis, each of said wing-like elements comprising first and second members having undulations

And claim 59 (from which claim 60 depends) recites:

a plurality of stretchable elements formed in the coiled-up sheet, wherein each stretchable element comprises a pair of peripherally expandable wing-like elements extending generally parallel to the longitudinal axis, each of said wing-like elements comprising first and second members having undulations.

Neither of these limitations is disclosed, taught, or suggested (either explicitly or by inherency) by the Fogarty patent. Nor does the Khosravi '515 patent supply the missing subject matter. Accordingly, because the Examiner has failed to establish that all of the

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limitations of the claims are found in the cited art as a whole, the Examiner has failed to establish a prima facie case of obviousness. For these reasons, Applicants respectfully request withdrawal of the rejections of these claims under section 103.

In addition, Applicant once again submits that the Examiner has failed to identify any teaching, either from the references or elsewhere, as to why a person of skill in the art would be motivated to combine the disparate teachings of these three patents in the manner done by the Examiner. In his response to Applicant's previous arguments on this issue, the Examiner stated his recognition that obviousness can be established by combining or modifying the teachings of the prior art only where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. The Examiner stated that, in this case, "[i]t would have been obvious to one of ordinary skill in the art to incorporate a plurality of locking elements in the coil sheet stent as taught by Khosravi et al. in the stent of Fogarty such that it remains in the enlarged condition and does not collapse in the patient." This is, quite simply, an inadequate finding upon which to reject the present claims.

To begin with, it matters not whether the features described in a first reference "can be said to improve" a device shown in a second reference. There would be very few patents granted if this were the standard for proving a prima facie case of obviousness. Indeed, this rationale represents pure hindsight reconstruction, which is improper. Sensonics, Inc. v. Aerosonic Corp., 81 F.3d 1350, 1358 (Fed. Cir. 1998). Instead, the Examiner must show why someone of skill in the art would be motivated to combine the

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specific teachings of the cited references in the manner relied upon. Here, that means that the Examiner must show some teaching that would have motivated a person of skill in the art to combine the locking teeth mechanisms described in the Khosravi patent with the stent structures described in the Fogarty patent, and to do so without regard to any of the contrary teachings contained in that reference. It is not enough to simply pick and choose these features from the reference disclosures and state that they represent desirable “improvements” and that, therefore, one would have been motivated to make the combination. See, e.g., WMS Gaming, Inc. v. International Game Technology, 184 F.3d 1339, 1359 (Fed. Cir. 1999). Against this standard, the Examiner has failed to demonstrate a prima facie case of obviousness, because such a showing cannot be made on the basis of these varied references. There simply is no teaching available, either from the references or elsewhere, that would supply the motivation to make the combination relied upon by the Examiner.

Applicant has previously submitted the Rule 132 Declaration of Eric Leopold, an expert in the art of stents and stent manufacturing. Mr. Leopold reviewed each of the Fogarty and Khosravi patents, as well as the Examiner’s prior contentions concerning whether a person of ordinary skill in the art would be motivated to combine their teachings. Mr. Leopold concluded that nothing in those patents or in the general knowledge of a person of ordinary skill in the art would have provided any suggestion or motivation to combine the references as the Examiner suggests. (See Leopold Decl., ¶ 7).

In fact, Mr. Leopold identifies information contained within those patents that would steer a person of ordinary skill in the art away from the Fogarty/Khosravi combination relied

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upon by the Examiner. It has consistently been held that obviousness cannot be found where the prior art teaches away from a claimed solution. See, e.g., Micro Chemical, Inc. v. Great Plains Chemical Co., 103 F.3d 1538, 1546 (Fed. Cir. 1997); Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1579 (Fed. Cir. 1997). Noting that the Khosravi patent teaches structures and locking mechanisms that increase the likelihood of fibrin accumulation and thrombosis, and that a stated objective of the stents described in the Fogarty patent was to minimize hyperplasia caused by the interaction of the stent with the interior wall of the vessel, Mr. Leopold concludes that the information contained in the Khosravi patent would actually steer one of ordinary skill in the art away from such a combination. (Leopold Decl., ¶ 14).

The mere fact that several of the elements of Applicant's claims may be found in the cited references is simply not enough to support a *prima facie* case of obviousness, see In re Rouffet, 149 F.3d 1350, 1358 (Fed. Cir. 1998), and is certainly an insufficient showing in comparison to the above evidence negating obviousness. Indeed, the only support for making the combination is to use Applicant's claims as a template, which is improper. Sensonics, 81 F.3d at 1570. For these reasons, Applicant respectfully requests reconsideration of the rejections made in the present Office Action, and allowance of claims 29-30, 56, and 60.

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CONCLUSION

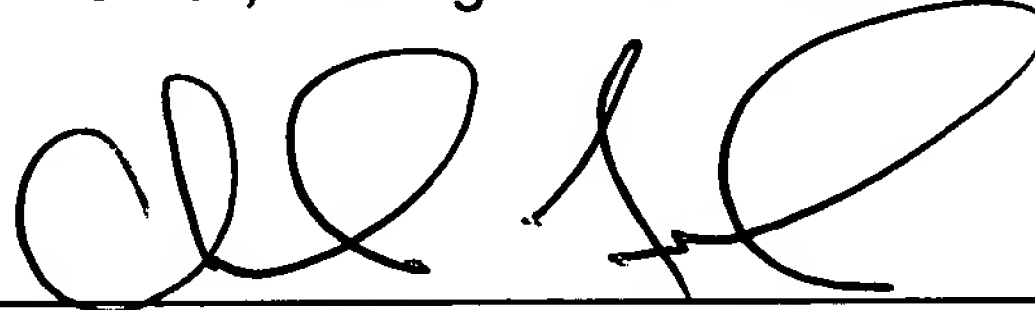
In view of the foregoing, it is submitted that the claims presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,

Orrick, Herrington & Sutcliffe LLP

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By

A handwritten signature in black ink, appearing to be 'Charles C. Fowler', written over a horizontal line.

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